



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1491]

Agency Information Collection Activities: Proposed Collection; Comment Request; Survey of Pharmacists and Patients; Variations in the Physical Characteristics of Generic Drug Pills and Patients' Perceptions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection associated with a survey of pharmacists and patients about their experiences resulting from changes in generic drug pill appearance.

DATES: Submit either electronic or written comments on the collection of information by

[INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER.]

ADDRESSES: Submit electronic comments on the collection of information to

<http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane., rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Survey of Pharmacists and Patients: Variations in the Physical Characteristics of Generic Drug Pills and Patients' Perceptions--(OMB Control Number 0910-NEW)

Generic drugs make up approximately 85 percent of all human prescription drugs prescribed in the United States. While generic drugs are required to be pharmaceutically equivalent and bioequivalent to their brand-name counterparts, generics made by different manufacturers may differ substantially from their brand-name therapeutic equivalents and from each other in their physical appearance (e.g., color, shape, or size of pills). When pharmacists switch generic drug suppliers, patients refilling their generic prescriptions may therefore experience changes in their drugs' appearances. These changes may result in patient confusion and concerns about the safety and effectiveness of the generic drug products. Studies indicate that patients are more likely to stop taking their generic medications when they experience a change in their drugs' physical appearances, leading to harmful clinical and public health consequences as well as increased health care costs from avoidable morbidity and mortality.

To provide additional information that may help guide regulatory policy or pharmacy business practices, we intend to conduct surveys of pharmacists and patients about their perceptions about and experiences with generic drug product pill appearance change. These surveys are intended to further our understanding of the relationship between changes in pill appearance and non-adherence to prescribed therapeutic regimens. The surveys may enable us to investigate factors that may explain the association between changes in pill appearance and non-adherence, including which factors could be modified to improve the safe and effective use of generic drugs.

We intend to survey a national cohort of pharmacists about their experiences with dispensing generic drug pills that differ in appearance from previous refills of the same medication and dosage level (e.g., when pharmacies switch generic suppliers). A stratified, random sample of U.S.-licensed pharmacists will be obtained based on a master list from KM

Lists. The target sample includes pharmacists with active licenses who practice in traditional community pharmacy settings and will be proportionally allocated across the United States in relation to the number of pharmacists in each state. Based on an 11 percent undeliverable rate and a 52 percent response rate, 2,161 questionnaires will be mailed to pharmacists to obtain the 1,000 responses required for adequate statistical power. The pharmacists' survey will consist of a mailed questionnaire rather than a telephone survey or an email survey. Prior experience conducting surveys has shown that it is easier to guarantee respondent anonymity using an impersonal, mailed questionnaire with no individual identifying information. The pharmacists will be asked about the frequency with which their pharmacy changes suppliers that lead to variations in the appearance of the generic drugs that they dispense, as well as strategies they use with patients to address the transition to pills that have a different appearance (e.g., alert stickers on pill bottles, verbal warnings, and other strategies). They will also be asked about patient responses to changes in pill appearance, including what types of appearance changes seem to affect patients most often (shape/color/size), how often patients report confusion about pill appearance, and how often patients ultimately refuse to accept the new product. Participation is expected to take approximately 20 minutes.

We also intend to survey two different patient samples using two methodologies. The first is a telephone survey of patients who are 50 years and older and who take one or more generic medications for at least one of the following chronic conditions: Epilepsy, diabetes, hypertension, hyperlipidemia, depression, and HIV. The telephone survey will be generalizable and will consist of well-defined methods to minimize sampling bias such as use of random phone numbers for both landlines and mobile phones, as well as small-batch sampling to ensure a high response rate that meets demographic diversity goals. For the second patient survey, patients

will be selected from a proprietary research database of commercially insured patients containing medical and pharmacy claims linked to health insurance enrollment information. A nationally representative sample of patients with at least one chronic condition and who experienced a change in physical appearance of a generic pill will be identified by the research team using medical and pharmacy claims data. Both patient surveys will consist of questions covering topics similar to those asked in the survey of pharmacists and is intended to provide answers to the same topic areas from patients' perspectives. As before, topic areas will include beliefs about generic drugs, outcomes related to changes in generic drug pill appearance, and strategies used by pharmacists or doctors to alert patients to the possibility of changes in appearance. Participation is expected to take approximately 20 minutes.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Reporting Burden<sup>1</sup>

Surveys of Pharmacists and Patients on Variations in the Physical Characteristics of Generic Drug Pills and Patients' Perceptions	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Survey of Pharmacists	1,000	1	1,000	0.333 (20 minutes)	333
Survey of Patients #1	1,000	1	1,000	0.333 (20 minutes)	333
Survey of Patients #2	1,000	1	1,000	0.333 (20 minutes)	333
Total					999

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-24365 Filed 10/14/2014 at 8:45 am; Publication Date: 10/15/2014]